REMARKS

Reconsideration of this application is respectfully requested.

STATUS OF THE CLAIMS

Following entry of this Amendment, claims 14 and 19-39 will be pending. Claim 14 has been amended. Claims 1-13 and 15-18 are cancelled. Claims 19-39 have been added.

Support for the new and amended claim is as follows:

Claim 14: page 14, lines 1-21; page 17, lines 30-36; and page 20, lines 23-36.

Claims 19-39: page 8, lines 19-30; Figure 2 (SEQ ID NO: 2); and Figure 4 (Metalloproteinase domain alignment of ADAMTS-E v. ADAMTS family).

The Commissioner is authorized to charge the above-mentioned deposit account the required amount for the newly added claims added exceeding 20.

INFORMALITIES

Applicants acknowledge the notice of draftsperson's patent drawing review (PTO-948) attached to the office action. Applicants wish to inform the Examiner that Applicants spoke with Mr. Ponnathapura Achutamurthy to discuss the requirements of 37 C.F.R. 1.85(a) on June 12, 2003. Mr. Achutamurthy informed the Applicants that pursuant to this rule the corrected drawings could be submitted following a notice of allowance.

REJECTION UNDER 35 U.S.C. §101

Claims 5 and 6 stand rejected under 35 U.S.C. §101 on the basis that the claimed invention is directed to non-statutory subject matter. Claims 5 and 6 are cancelled. Reconsideration of the rejection is respectfully requested in view of the newly added claims 19-39.

The Examiner states that "[W]here claim 5 describes a polypeptide encoded by the isolated polynucleotide molecule of claim 1 it fails to distinguish a claimed product from a native

ADAMTS-E occurring naturally in human cells and claim 6 does not improve the description of claim 5." The Examiner further states that "should the specification provide support for description of an 'isolated' or of a 'purified' polypeptide, amending claim 5 with either term to describe a polypeptide removed from Nature will overcome this aspect of the rejection."

In response to this rejection Applicants have added new claim 19 which recites that the polypeptide is "isolated" and Applicants assert that this claim as currently presented fully addresses this rejection. Applicants respectfully refer the Examiner to page 14, lines 1-21, page 17, lines 30-36, and page 20, lines 23-36 for support regarding the isolation of this protein. The claim as now presented is drawn to the isolated polypeptide and is therefore statutory subject matter because it is a purified polypeptide not found in nature.

In view of these arguments, Applicants request that the rejection of claims 5 and 6 under 35 U.S.C. §101 be withdrawn.

Claims 5, 6 and 14 stand rejected under 35 U.S.C. §101 on the basis that the claimed invention lack patentable utility. Reconsideration of the rejection is respectfully requested. The Examiner states that "[W]hile the specification proposes potential diagnostic, prognostic, treatment, and screening uses, both *in vitro* and *in vivo*, for a native ADAMTS-E-which uses may be substantial if they were specific and demonstrated-the specification fails to identify a specific and substantial utility for the elected subject matter of claims 5, 6 and 14 at the time the application was filed."

Applicants respectfully refer the Examiner to the Revised USPTO Utility Examination Guidelines regarding imputed utility.[1] The Guidelines state that "when a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein." The polypeptide of the present invention is a member of the family of proteins known as ADAMTS proteins. ADAMTS proteins exhibit characteristics of the well-characterized ADAM family of metalloproteases.

[1] Department of Commerce, USPTO Utility Examination Guidelines, December 29, 2000

Members of this family of proteins have the ability to degrade aggrecan, a high molecular weight proteoglycan which provides cartilage with important mechanical properties and which is lost during the development of arthritis. Applicants respectfully refer the Examiner to Figure 4 illustrating the metalloproteinase domain alignment of ADAMTS-E to other members of the ADAMTS family as support for imputing utility to the protein of the present invention based on activity of members of the ADAMTS family. Applicants further refer the Examiner to page 1, lines 17-37 and page 2 lines 1-21 for a disclosure of other ADAMTS activities such as brevicanase activity and antiangiogenic activity which have been identified as having important roles in human disease. Applicants further refer the Examiner to page 21, lines 17-33 for a detailed disclosure of well-known assays for identifying activities of the polypeptide of the present invention. Applicants assert that a person of skill in the art would find readily apparent these activities and would be able without undue experimentation to assay for these activities using techniques known in the art.

Applicants further refer the Examiner to the Revised USPTO Utility Examination Guidelines[2] regarding homology based assertions of utility and wish to remind the Examiner that the proposed rule rejecting homology based assertions of utility was not adopted. The Guidelines state that an Examiner "must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion... when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner... . A rigorous correlation need not be shown in order to establish practical utility; reasonable correlation is sufficient."[3] The polypeptide of the present invention shares 31-59% identity in the metalloprotease domain as compared to other ADAMTS family members further supporting Applicant's statement of utility.

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[2] Department of Commerce, USPTO Utility Examination Guidelines, December 29, 2000.
[3] Fujikawa v. Wattanasin, 93 F 3d 1559, 1565 (Fed. Cir. 1996).

In view of these arguments, Applicants request that the rejection of claims 5, 6, and 14 under 35 U.S.C. §101 be withdrawn.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 5, 6 and 14 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. The primary basis for the rejection appears to be that the claimed invention of claims 5, 6, and 14 is not supported by either a specific asserted utility or a well established utility and one skilled in the art would not know how to use the claimed invention.

In view of the arguments presented above with respect to utility, Applicants respectfully assert that this is no longer a valid rejection and request withdrawal of the rejection of claims 5, 6 and 14 under 35 U.S.C. §112, first paragraph for lack of enablement.

The Examiner has also rejected claims 5, 6, and 14 as lacking written description. New claims 19-39 have been added so that, it is submitted, they encompass a narrow scope of subject mater that is easily envisioned by one skilled in this art. The scope of claims is such, it is submitted, that the functional characteristics of the invention are supported by Applicants' disclosure of the sequences shown, and activities of the particular domains described. Therefore, withdrawal of the rejection on this basis is respectfully requested.

The Examiner has further rejected claims 5, 6, and 14 because "the specification is not enabling for any embodiment of human protease having an amino acid sequence that diverges from the amino acid sequence of SEQ ID NO: 2 by amino acid substitutions, deletions and insertions, or combinations thereof at as many as 60% of the amino acid positions of any of SEQ ID NO: 2."

In response to this rejection, new claims 19-39 have been added which, Applicants believe address the bases of the Examiner's rejection. Specifically, the newly added claims encompass a narrow scope of subject mater. One skilled in the art would, it is submitted, readily be able to create and use the variants within the relatively narrow range encompassed. Applicants assert that the claims as now presented are sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation.

In view of the newly added claims, the amendment of claim 14, and comments above, withdrawal of the rejection of claims 5, 6, and 14 under 35 U.S.C. §112, first paragraph for lack of enablement is respectfully requested.

REJECTION S UNDER 35 U.S.C. §102(e)

Claims 5, 6 and 14 stand rejected under 35 U.S.C. §102(e) as anticipated by Apte et al., U. S. Patent No. 6,391,610 (hereinafter the '610 patent).

This rejection is based on the disclosed amino acid sequence of the human ADAMTS-10 zinc metalloprotease, which shares 88% identity with the amino acid sequence of the human ADAMTS-E polypeptide depicted in SEQ ID NO: 2, and the disclosed nucleic acid sequence which is 93% identical to SEQ ID NO: 1 of the present invention. The '610 patent further discloses the use of ADAMTS polypeptides in assays to identify compounds capable of inhibiting ADAMTS polypeptide activity.

In response to this rejection, Applicants have cancelled claims 5 and 6 and added claims 19-39. These new claims narrow the breadth of the subject matter being claimed and Applicants assert the claims are patentably distinct over the prior art. Specifically, language relating to percentage identity of the amino acid sequence of the individual domains to the disclosed amino acid sequence of SEQ ID NO: 2 was added. Applicants respectfully remind the Examiner that in the Office Action he states that narrowing the scope of the claims would "permit allowance of claims to such discrete subject matters." Applicants assert that the new claims encompass a narrow scope of subject mater and respectfully request withdrawal of the rejection of claims 5, 6, and 14 as anticipated by the '610 patent.

Claims 5, 6 and 14 stand rejected under 35 U.S.C. §102(e) as anticipated by Heller et al., published U.S. patent Application No. 2002 0107361 (hereinafter "Heller").

This rejection is based on the disclosure of the amino acid sequences of several human zinc metalloproteases related to the ADAMTS family which share 72.3% identity with the amino acid sequence of the present invention.

In response to this rejection, Applicants assert that claims 5, 6, and 14 are entitled to a filing date of April 26, 2000. As Examiner points out in the office action, the Heller application was filed after Applicant's April 26, 2000 filing date for the provisional application for which priority is claimed.

Withdrawal of the rejection of claims 5, 6, and 14 as anticipated by Heller et al. is respectfully requested.

CONCLUSION

This application is submitted to now be in condition for allowance. Issuance of a notice to that effect is respectfully requested.

Respectfully submitted,

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